Novartis Consumer Health, Inc.

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Form Approved by FDA on: 01/05/94

Mfr report # 0267416A

UF/Dist report #

FDA Use Only

A. Patient information

1. Patient identifier	2. Age at time of event: 50 or ____ Date of birth: 06/01/49	3. Sex	4. Weight
[redacted] In confidence		☒ female ☐ male	223 lbs or ____ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcome attributed to adverse event (check all that apply)

- ☐ death ____ (mo/day/yr)
- ☐ life-threatening
- ☒ hospitalization-initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ____

3. Date of event (mo/day/yr): 01/27/00

4. Date of this report (mo/day/yr): 02/09/00

5. Describe event or problem

THERAFLU HotLiq FC&C MS Nite Lemon;green: 08FEB2000 - Consumer took Theraflu one packet QD for two days beginning on 27JAN2000 for a headache and fever of 102 degrees. Her headache resolved and her fever continued. On 29JAN2000 she developed shortness of breath, followed in the next few days with a dry hacking cough, bloating, upset stomach, liver engorgement and distension. She saw her gynecologist on 03FEB2000 and a liver function test revealed elevated enzymes, CBC revealed elevated WBC and chest x-ray showed cardiomegaly. An ECG was done by her internist and it was abnormal. The internist admitted her to the hospital on 04FEB2000. An ECG was done which showed fluid in the pericardium and Pericarditis was diagnosed. Pericardiocentesis drained about 350cc of fluid. Normal saline IV fluid was administered and barium was given for CAT Scan. The CAT scan revealed some lung changes associated with radiation and no masses or growth. She was discharged on 07FEB2000.

6. Relevant tests/laboratory data, including dates

02FEB2000-Chest X-ray cardiomegaly, LFT-elevated liver enzymes, CBC-elevated WBC 03FEB2000-ECG abnormal, 04FEB2000-ECG showed fluid in the pericardium

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Cholecystectomy, human papilloma virus in the mouth, heart murmur, 1984-85 R simple masectomy, L radical masectomy with left pectoral muscle and lymph nodes removed,

CONTINUED

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 T/FLU-APAP1GM,DEX30MG,PSE60MG,CHL4MG-NvCH
#2

2. Dose, frequency & route used
#1 1 packet/QD/PO
#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 01/27/00 - 01/28/00
#2

4. Diagnosis for use (indication)
#1 Headache, fever
#2

5. Event abated after use stopped or dose reduced
#1 ☐ yes ☐ no ☒ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#1 25635
#2

7. Exp. date (if known)
#1 03/31/02
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☒ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # — for product only (if known)
N/A

10. Concomitant medical products and therapy dates (exclude treatment of event)
Aspirin, Vitamin C, One-A-Day Fifty Plus Multivitamin

G. All manufacturers

1. Contact office — name/address (& mfring site for devices)
Novartis Consumer Health, Inc.
560 Morris Ave.
Summit, NJ 07901-1312

2. Phone number: 908-602-6730

3. Report source (check all that apply)
- ☐ foreign
- ☐ study
- ☐ literature
- ☒ consumer
- ☐ health professional
- ☐ user facility
- ☐ company representative
- ☐ distributor
- ☐ other: ____

4. Date received by manufacturer (mo/day/yr): 02/08/00

5. (A) NDA # NO NDA
IND # ____
PLA # ____
pre-1938 ☐ yes
OTC product ☒ yes

6. If IND, protocol #
N/A

7. Type of report (check all that apply)
- ☐ 5-day ☒ 15-day
- ☐ 10-day ☐ periodic
- ☒ Initial ☐ follow-up # ____

8. Adverse event term(s)
COUGHING, FLATULENCE, DYSPNEA DYSPEPSIA, HEPATOMEGALY, HEPATIC FUNCTION ABNORMAL, FEVER, PERICARDITIS, LAB ABN-HEMATOLOGY, CARDIOMEGALY

9. Mfr. report number
0267416A

E. Initial reporter

1. Name, address & phone #
[redacted]

DSS

FEB 2 9 2000

FEB 2 9 2000

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
☐ yes ☒ no	N/A	☐ yes ☒ no ☐ unk

FDA

Facsimile of FDA Form 3500A

Submission of a report does not consitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Novartis Consumer Health, Inc.
MFR Report # 0267416A
Patient Initials: [redacted]

CONTINUATION OF B7: malignant lung tumor in lower right lobe removed, lower right lobe removed, allergic to Thorazine